



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Parts 9, 721, and 725

[EPA-HQ-OPPT-2018-0777; FRL-10023-11]

RIN 2070-AB27

### Significant New Use Rules on Certain Chemical Substances (19-1.F)

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** EPA is issuing significant new use rules (SNURs) under the Toxic Substances Control Act (TSCA) for chemical substances which were the subject of premanufacture notices (PMNs) and a microorganism that was the subject of a Microbial Commercial Activity Notice (MCAN). This action requires persons to notify EPA at least 90 days before commencing manufacture (defined by statute to include import) or processing of any of these chemical substances for an activity that is designated as a significant new use by this rule. This action further requires that persons not commence manufacture or processing for the significant new use until they have submitted a Significant New Use Notice (SNUN), and EPA has conducted a review of the notice, made an appropriate determination on the notice, and has taken any risk management actions as are required as a result of that determination.

**DATES:** This rule is effective on [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. For purposes of judicial review, this rule shall be promulgated at 1 p.m. (e.s.t.) on [INSERT DATE 14 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**FOR FURTHER INFORMATION CONTACT:** *For technical information contact:* William Wysong, New Chemicals Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-4163; email address: [wysong.william@epa.gov](mailto:wysong.william@epa.gov).

*For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: [TSCA-Hotline@epa.gov](mailto:TSCA-Hotline@epa.gov).*

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. Does this action apply to me?*

You may be potentially affected by this action if you manufacture, process, or use the chemical substances contained in this rule. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Manufacturers or processors of one or more subject chemical substances (NAICS codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import provisions. This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA, which would include the SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, pursuant to 40 CFR 721.20 (or 40 CFR 725.920 for the MCAN substance), any persons who export or intend to export a chemical substance that is the subject of this rule are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

#### *B. How can I access the docket?*

The docket includes information considered by the Agency in developing the proposed and final rules. The docket for this action, identified by docket identification (ID) number EPA-

HQ-OPPT-2018-0777, is available at <https://www.regulations.gov> and at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Please review the visitor instructions and additional information about the docket available at <https://www.epa.gov/dockets>.

Due to the public health emergency, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

## **II. Background**

### *A. What action is the Agency taking?*

EPA is finalizing SNURs under TSCA section 5(a)(2) for chemical substances which were the subject of PMNs P-17-382, P-18-41, P-18-70, P-18-100, P-18-102, P-18-116, P-18-136, P-18-137, P-18-219, P-18-224, P-18-225, P-18-233, P-18-279, and of MCAN J-18-41. These SNURs require persons who intend to manufacture or process any of these chemical substances for an activity that is designated as a significant new use to notify EPA at least 90 days before commencing that activity.

Previously, in the *Federal Register* of July 31, 2019 (84 FR 37199) (FRL-9994-62), EPA proposed SNURs for these chemical substances. EPA will address the other proposed SNURs in a subsequent *Federal Register* document. More information on the specific chemical substances subject to this final rule can be found in the *Federal Register* document proposing the SNURs. The docket includes information considered by the Agency in developing the proposed and final rules, including the public comments received on the proposed rules that are described in Unit

#### IV.

##### *B. What is the Agency's authority for taking this action?*

TSCA section 5(a)(2) (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a “significant new use.” EPA must make this determination by rule after considering all relevant factors, including the four TSCA section 5(a)(2) factors listed in Unit III.A.

##### *C. Do the SNUR general provisions apply?*

General provisions for SNURs appear in 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the rule. Provisions relating to user fees appear at 40 CFR part 700. Pursuant to 40 CFR 721.1(c), persons subject to these SNURs must comply with the same SNUN requirements and EPA regulatory procedures as submitters of PMNs under TSCA section 5(a)(1)(A). In particular, these requirements include the information submission requirements of TSCA sections 5(b) and 5(d)(1), the exemptions authorized by TSCA sections 5(h)(1), 5(h)(2), 5(h)(3), and 5(h)(5) and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA must either determine that the significant new use is not likely to present an unreasonable risk of injury or take such regulatory action as is associated with an alternative determination before manufacture or processing for the significant new use can commence. If EPA determines that the significant new use is not likely to present an unreasonable risk, EPA is required under TSCA section 5(g) to make public, and submit for publication in the *Federal Register*, a statement of EPA’s findings.

### **III. Significant New Use Determination**

#### *A. Determination Factors*

TSCA section 5(a)(2) states that EPA’s determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors, including:

- The projected volume of manufacturing and processing of a chemical substance.

- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In determining what would constitute a significant new use for the chemical substances that are the subject of these SNURs, EPA considered relevant information about the toxicity of the chemical substances and potential human exposures and environmental releases that may be associated with the substances, in the context of the four bulleted TSCA section 5(a)(2) factors listed in this unit.

During its review of the chemical substances that are the subjects of these SNURs and as further discussed in Unit VI., EPA identified potential risk concerns associated with other circumstances of use that, while not intended or reasonably foreseen, may occur in the future. EPA is designating those other circumstances of use as significant new uses.

*B. Procedures for significant new uses claimed as confidential business information (CBI)*

By this rule, EPA is establishing certain significant new uses which have been claimed as CBI subject to Agency confidentiality regulations at 40 CFR part 2 and 40 CFR part 720, subpart E. Absent a final determination or other disposition of the confidentiality claim under 40 CFR part 2 procedures, EPA is required to keep this information confidential. EPA promulgated a procedure to deal with the situation where a specific significant new use is CBI, at 40 CFR 721.1725(b)(1) and has referenced it to apply to other SNURs.

Under these procedures a manufacturer or processor may request EPA to determine whether a specific use would be a significant new use under the rule. The manufacturer or processor must show that it has a *bona fide* intent to manufacture or process the chemical substance and must identify the specific use for which it intends to manufacture or process the

chemical substance. If EPA concludes that the person has shown a *bona fide* intent to manufacture or process the chemical substance, EPA will tell the person whether the use identified in the *bona fide* submission would be a significant new use under the rule. Since most of the chemical identities of the chemical substances subject to these SNURs are also CBI, manufacturers and processors can combine the *bona fide* submission under the procedure in 40 CFR 721.1725(b)(1) with that under 40 CFR 721.11 into a single step.

If EPA determines that the use identified in the *bona fide* submission would not be a significant new use, i.e., the use does not meet the criteria specified in the rule for a significant new use, that person can manufacture or process the chemical substance so long as the significant new use trigger is not met. In the case of a production volume trigger, this means that the aggregate annual production volume does not exceed that identified in the *bona fide* submission to EPA. Because of confidentiality concerns, EPA does not typically disclose the actual production volume that constitutes the use trigger. Thus, if the person later intends to exceed that volume, a new *bona fide* submission would be necessary to determine whether that higher volume would be a significant new use.

#### **IV. Public Comments**

EPA received public comments from two identifying entities on the proposed rule. The Agency's responses are presented in the Response to Public Comments document that is available in the docket for this rule. EPA did not make changes to any of the proposed rules as a result of these comments. Separately, EPA made changes to the SNUR proposed at 40 CFR 725.1079 for the microorganism which was the subject of MCAN J-18-41. This SNUR, as proposed, included references to 40 CFR part 721. These have been changed to refer instead to the equivalent provisions in 40 CFR part 725, concerning reporting requirements and review processes for microorganisms. The effect of the SNUR has not been altered by these changes.

#### **V. Substances Subject to this Rule**

EPA is establishing significant new use and recordkeeping requirements for chemical

substances in 40 CFR part 721, subpart E, for several chemicals that were the subject of PMNs, and in 40 CFR part 725 for one chemical substance that is a microorganism (MCAN J-18-41). In Unit IV. of the proposed SNUR, EPA provided the following information for each chemical substance:

- PMN or MCAN number.
- Chemical name (generic name, if the specific name is claimed as CBI).
- Chemical Abstracts Service (CAS) Registry number (if assigned for non-confidential chemical identities).
- Basis for the SNUR.
- Potentially useful information.
- CFR citation proposed to be assigned in the regulatory text section. This final rule makes the final assignment to set the CFR citation for the chemical.

The regulatory text section of these rules specifies the activities designated as significant new uses. Certain new uses, including production volume limits and other uses designated in the rules, may be claimed as CBI.

## **VI. Rationale and Objectives of the Rule**

### *A. Rationale*

The chemical substances that are the subjects of these SNURs received “not likely to present an unreasonable risk” determinations under TSCA section 5(a)(3)(C) based on EPA’s review of the intended, known, and reasonably foreseen conditions of use. However, EPA has identified other circumstances that, should they occur in the future, even if not reasonably foreseen, may present risk concerns. Specifically, EPA has determined that deviations from the protective measures identified in the PMN submissions could result in changes in the type or form of exposure to the chemical substances, increased exposures to the chemical substances, and/or changes in the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of the chemical substances. These SNURs identify as a

significant new use manufacturing, processing, use, distribution in commerce, or disposal that does not conform to the protective measures identified in the submissions. As a result, those significant new uses cannot occur without first going through a separate, subsequent EPA review and determination process associated with a SNUN.

### *B. Objectives*

EPA is issuing these SNURs because the Agency wants:

- To have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing or processing a listed chemical substance for the described significant new use.
- To be obligated to make a determination under TSCA section 5(a)(3) regarding the use described in the SNUN, under the conditions of use. The Agency will either determine under TSCA section 5(a)(3)(C) that the significant new use is not likely to present an unreasonable risk, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, or make a determination under TSCA section 5(a)(3)(A) or (B) and take the required regulatory action associated with the determination, before manufacture or processing for the significant new use of the chemical substance can occur.

Issuance of a SNUR for a chemical substance does not signify that the chemical substance is listed on the TSCA Inventory. Guidance on how to determine if a chemical substance is on the TSCA Inventory is available on the Internet at <https://www.epa.gov/tscainventory>.

## **VII. Applicability of the Rules to Uses Occurring Before the Effective Date of the Final Rule**

To establish a significant new use, EPA must determine that the use is not ongoing. The chemical substances subject to this rule have undergone premanufacture review. In cases where EPA has not received a notice of commencement (NOC) and the chemical substance has not



been added to the TSCA Inventory, no person may commence such activities without first submitting a PMN. Therefore, for chemical substances for which an NOC has not been submitted, EPA concludes that the designated significant new uses are not ongoing.

When the chemical substances identified in this rule are added to the TSCA Inventory, EPA recognizes that, before the rule is effective, other persons might engage in a use that has been identified as a significant new use. However, the identities of many of the chemical substances subject to this rule have been claimed as confidential (per 40 CFR 720.85). Based on this, the Agency believes that it is highly unlikely that any of the significant new uses described in the regulatory text of this rule are ongoing.

EPA designated July 31, 2019 (the date of FR publication of the proposed rule) as the cutoff date for determining whether the new use is ongoing. The objective of EPA's approach is to ensure that a person cannot defeat a SNUR by initiating a significant new use before the effective date of the final rule.

Persons who began commercial manufacture or processing of the chemical substances for a significant new use identified on or after that date will have to cease any such activity upon the effective date of the final rule. To resume their activities, these persons would have to first comply with all applicable SNUR notification requirements and EPA would have to take action under section 5 allowing manufacture or processing to proceed.

### **VIII. Development and Submission of Information**

EPA recognizes that TSCA section 5 does not require development of any particular new information (*e.g.*, generating test data) before submission of a SNUN. There is an exception: If a person is required to submit information for a chemical substance pursuant to a rule, Order or consent agreement under TSCA section 4, then TSCA section 5(b)(1)(A) requires such information to be submitted to EPA at the time of submission of the SNUN.

In the absence of a rule, Order, or consent agreement under TSCA section 4 covering the chemical substance, persons are required only to submit information in their possession or

control and to describe any other information known to or reasonably ascertainable by them (see 40 CFR 720.50). However, upon review of PMNs and SNUNs, the Agency has the authority to require appropriate testing. Unit IV. of the proposed rule lists potentially useful information for all SNURs listed here. Descriptions are provided for informational purposes. The potentially useful information identified in Unit IV. of the proposed rule will be useful to EPA's evaluation in the event that someone submits a SNUN for the significant new use. Companies who are considering submitting a SNUN are encouraged, but not required, to develop the information on the substance, which may assist with EPA's analysis of the SNUN.

EPA strongly encourages persons, before performing any testing, to consult with the Agency pertaining to protocol election. Furthermore, pursuant to TSCA section 4(h), which pertains to reduction of testing in vertebrate animals, EPA encourages consultation with the Agency on the use of alternative test methods and strategies (also called New Approach Methodologies, or NAMs), if available, to generate the recommended test data. EPA encourages dialog with Agency representatives to help determine how best the submitter can meet both the data needs and the objective of TSCA section 4(h). For more information on alternative test methods and strategies to reduce vertebrate animal testing, visit <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/alternative-test-methods-and-strategies-reduce>.

The potentially useful information described in Unit IV. of the proposed rule may not be the only means of providing information to evaluate the chemical substance associated with the significant new uses. However, submitting a SNUN without any test data may increase the likelihood that EPA will take action under TSCA sections 5(e) or 5(f). EPA recommends that potential SNUN submitters contact EPA early enough so that they will be able to conduct the appropriate tests.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs which provide detailed information on the following:

- Human exposure and environmental release that may result from the significant new use

of the chemical substances.

## **IX. SNUN Submissions**

According to 40 CFR 721.1(c), persons submitting a SNUN must comply with the same notification requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in 40 CFR 720.50. SNUNs must be submitted on EPA Form No. 7710-25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in 40 CFR 720.40. According to 40 CFR 725.900, persons submitting an MCAN for a significant new use of a microorganism must comply with the same notification requirements and EPA regulatory procedures as persons submitting an MCAN for a new microorganism, including submission of test data on health and environmental effects as described in 40 CFR 725.160. E-PMN software is available electronically at <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca>.

## **X. Economic Analysis**

EPA has evaluated the potential costs of establishing SNUN requirements for potential manufacturers and processors of the chemical substances subject to this rule. EPA's complete economic analysis is available in the docket for this rulemaking.

## **XI. Statutory and Executive Order Reviews**

Additional information about these statutes and Executive orders can be found at <https://www.epa.gov/laws-regulations-and-executive-orders>.

*A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulations and Regulatory Review*

This action establishes SNURs for new chemical substances that were the subject of PMNs. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011).

### *B. Paperwork Reduction Act (PRA)*

According to the PRA, 44 U.S.C. 3501 *et seq.*, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the *Federal Register*, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable.

The information collection requirements related to this action have already been approved by OMB pursuant to PRA under OMB control number 2070-0012 (EPA ICR No. 574). This action does not impose any burden requiring additional OMB approval. If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average between 30 and 170 hours per response. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

The listing of the OMB control numbers of the collection instruments and their subsequent codification in the table in 40 CFR 9.1 satisfies the display requirements of the PRA and OMB's implementing regulations at 5 CFR part 1320. Since this ICR was previously subject to public notice and comment prior to OMB approval, and given the technical nature of the table in 40 CFR part 9, EPA finds that further notice and comment to amend it is unnecessary. As a result, EPA finds that there is "good cause" under section 553(b)(3)(B) of the Administrative Procedure Act (5 U.S.C. 553(b)(3)(B)) to amend this table in 40 CFR 9.1 without further notice and comment.

### *C. Regulatory Flexibility Act (RFA)*

Pursuant to the RFA section 605(b), 5 U.S.C. 601 *et seq.*, I hereby certify that promulgation of this SNUR does not have a significant adverse economic impact on a substantial number of small entities. The requirement to submit a SNUN applies to any person (including

small or large entities) who intends to engage in any activity described in the final rule as a “significant new use”. Because these uses are “new,” based on all information currently available to EPA, it appears that no small or large entities presently engage in such activities. A SNUR requires that any person who intends to engage in such activity in the future must first notify EPA by submitting a SNUN. Although some small entities may decide to pursue a significant new use in the future, EPA cannot presently determine how many, if any, there may be. However, EPA’s experience to date is that, in response to the promulgation of SNURs covering over 1,000 chemicals, the Agency receives only a small number of notices per year. For example, the number of SNUNs received was seven in Federal fiscal year (FY) 2013, 13 in FY2014, six in FY2015, 12 in FY2016, 13 in FY2017, and 11 in FY2018. Only a fraction of these were from small businesses. In addition, the Agency currently offers relief to qualifying small businesses by reducing the SNUN submission fee from \$16,000 to \$2,800. This lower fee reduces the total reporting and recordkeeping of cost of submitting a SNUN to about \$10,116 for qualifying small firms. Therefore, the potential economic impacts of complying with this SNUR are not expected to be significant or adversely impact a substantial number of small entities. In a SNUR that published in the *Federal Register* of June 2, 1997 (62 FR 29684) (FRL-5597-1), the Agency presented its general determination that final SNURs are not expected to have a significant economic impact on a substantial number of small entities, which was provided to the Chief Counsel for Advocacy of the Small Business Administration.

#### *D. Unfunded Mandates Reform Act (UMRA)*

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal government will be impacted by this action. As such, EPA has determined that this action does not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of UMRA sections 202, 203, 204, or 205 (2 U.S.C. 1501 *et seq.*).

*E. Executive Order 13132: Federalism*

This action does not have federalism implications because it is not expected to have a substantial direct effect on States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999).

*F. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments*

This action will not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes, significantly or uniquely affect the communities of Indian Tribal governments, and does not involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175 (65 FR 67249, November 9, 2000), do not apply to this action.

*G. Executive Order 13045: Protection of Children from Environmental Health and Safety Risks*

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children.

*H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use*

This action is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because this action is not a significant regulatory action under Executive Order 12866.

*I. National Technology Transfer and Advancement Act (NTTAA)*

Since this action does not involve any technical standards, NTTAA section 12(d), 15 U.S.C. 272 note, does not apply to this action.

*J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations*

This action does not entail special considerations of environmental justice related issues

as delineated by Executive Order 12898 (59 FR 7629, February 16, 1994).

*K. Congressional Review Act (CRA)*

This action is subject to the CRA (5 U.S.C. 801 *et seq.*), and EPA will submit a rule report containing this rule and other required information to each House of the Congress and to the Comptroller General of the United States. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects**

*40 CFR Part 9*

Environmental protection, Reporting and recordkeeping requirements.

*40 CFR Parts 721 and 725*

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: April 22, 2021.

**Tala Henry,**

*Deputy Director, Office of Pollution Prevention and Toxics.*

Therefore, for the reasons stated in the preamble, 40 CFR chapter I is amended as follows:

## **PART 9--OMB APPROVALS UNDER THE PAPERWORK REDUCTION ACT**

1. The authority citation for part 9 continues to read as follows:

**Authority:** 7 U.S.C. 135 *et seq.*, 136-136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601-2671; 21 U.S.C. 331j, 346a, 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.*, 1311, 1313d, 1314, 1318, 1321, 1326, 1330, 1342, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971-1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g-1, 300g-2, 300g-3, 300g-4, 300g-5, 300g-6, 300j-1, 300j-2, 300j-3, 300j-4, 300j-9, 1857 *et seq.*, 6901-6992k, 7401-7671q, 7542, 9601-9657, 11023, 11048.

2. In § 9.1, amend the table by adding entries for §§ 721.11278, 721.11282, 721.11283, 721.11285 through 721.11287, 721.11289 through 721.11294, and 721.11603 in numerical order under the undesignated center heading “Significant New Uses of Chemical Substances” to read as follows:

### **§ 9.1 OMB approvals under the Paperwork Reduction Act.**

\* \* \* \* \*

<b>40 CFR citation</b>	<b>OMB control No.</b>
* * * *	* * *
Significant New Uses of Chemical Substances	
* * * *	* *
721.11278	2070-0012
721.11282	2070-0012
721.11283	2070-0012
721.11285	2070-0012
721.11286	2070-0012
721.11287	2070-0012
721.11289	2070-0012
721.11290	2070-0012
721.11291	2070-0012
721.11292	2070-0012
721.11293	2070-0012
721.11294	2070-0012
* * * *	* * *
721.11603	2070-0012
* * * *	* * *



\* \* \* \* \*

## PART 721--SIGNIFICANT NEW USES OF CHEMICAL SUBSTANCES

3. The authority citation for part 721 continues to read as follows:

**Authority:** 15 U.S.C. 2604, 2607, and 2625(c).

4. Add §§ 721.11278, 721.11282, 721.11283, 721.11285 through 721.11287, 721.11289 through 721.11294, and 721.11603 to subpart E to read as follows:

### Subpart E Significant New Uses for Specific Chemical Substances

Sec.

\* \* \* \* \*

721.11278 Amides, tallow, N,N-bis(2-hydroxypropyl).

721.11282 2,5-Furandione, polymer with 2-ethyl-2-(hydroxymethyl)-1,3-propanediol, 3a,4,5,6,7,7a-hexahydro-4,7-methano-1H-inden-5(or 6)-yl ester, ester with 2,3-dihydroxypropyl neodecanoate.

721.11283 Waste plastics, polyester, depolymd. with glycols, polymers with dicarboxylic acids (generic).

721.11285 Substituted alkanolic acid, polymer with alkylcarbonate, alkanediols and isocyanate substituted carbomonocycles, sodium salt, alkenic acid substituted polyol reaction products-blocked (generic).

721.11286 Alkenic acid, ester with [oxybis(alkylene)]bis[alkyl-substituted alkanediol], polymer with alkylcarbonate, alkanediols, substituted alkanolic acid and isocyanate and alkyl substituted carbomonocycle, sodium salt (generic).

721.11287 Castor oil, reaction products with soybean oil.

721.11289 1-Butanaminium,N,N,N-tributyl-,2(or 5)- [[benzoyldihydrodioxo [(sulfophenyl) amino]heteropolycycle]oxy]-5(or 2)-(1,1-dimethylpropyl)benzenesulfonate (2:1) (generic).

721.11290 Alkylsilsesquioxane, ethoxy-terminated (generic).

721.11291 Polythioether, short chain diol polymer terminated with aliphatic diisocyanate (generic).

721.11292 Alkenic acid, polymer with alkenylcarbomonocycle, [alkanediylbis (substituted alkylene)] bis[heteromonocycle] and (alkylalkenyl) aromatic, salt (generic).

721.11293 Alkenic acid, polymer with substituted alkyloxirane, alkenylcarbomonocycle, alkyl substituted alkyl alkanediol and (alkylalkenyl) aromatic, salt (generic).

721.11294 Alkyl alkenic acid, alkyl ester, telomer with alkylthiol, substituted carbomonocycle, substituted alkyl alkyl alkenoate and hydroxyalkyl alkenoate, tertbutyl alkyl peroxyate-initiated (generic).

\* \* \* \* \*

721.11603 Substituted heteromonocycle, polymer with substituted alkanediol and diisocyanate substituted carbomonocycle, alkylene glycol acrylate-blocked (generic).

\* \* \* \* \*

### § 721.11278 Amides, tallow, N,N-bis(2-hydroxypropyl).

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical

substance identified as amides, tallow, N,N-bis(2-hydroxypropyl) (PMN P-17-382; CAS No. 1454803-04-3) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposures. It is a significant new use to process the substance resulting in an end use product containing greater than 3% by weight of the substance.

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=11.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

**§ 721.11282 2,5-Furandione, polymer with 2-ethyl-2-(hydroxymethyl)-1,3-propanediol, 3a,4,5,6,7,7a-hexahydro-4,7-methano-1H-inden-5(or 6)-yl ester, ester with 2,3-dihydroxypropyl neodecanoate.**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as 2,5-Furandione, polymer with 2-ethyl-2-(hydroxymethyl)-1,3-propanediol, 3a,4,5,6,7,7a-hexahydro-4,7-methano-1H-inden-5(or 6)-yl ester, ester with 2,3-dihydroxypropyl neodecanoate (PMN P-18-41) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in §

721.80(g). It is a significant new use to manufacture (including import) the substance with the number average molecular weight of less than 1000 daltons.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

**§ 721.11283 Waste plastics, polyester, depolymd. with glycols, polymers with dicarboxylic acids (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as waste plastics, polyester, depolymd. with glycols, polymers with dicarboxylic acids (PMN P-18-70) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(j).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) though (c) and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of §

721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.

**§ 721.11285 Substituted alkanolic acid, polymer with alkylcarbonate, alkanediols and isocyanate substituted carbomonocycles, sodium salt, alkenolic acid substituted polyol reaction products-blocked (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as substituted alkanolic acid, polymer with alkylcarbonate, alkanediols and isocyanate substituted carbomonocycles, sodium salt, alkenolic acid substituted polyol reaction products-blocked (PMN P-18-100) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f), (j), and (o).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.

**§ 721.11286 Alkenolic acid, ester with [oxybis(alkylene)]bis[alkyl-substituted alkanediol], polymer with alkylcarbonate, alkanediols, substituted alkanolic acid and isocyanate and alkyl substituted carbomonocycle, sodium salt (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as alkenolic acid, ester with [oxybis(alkylene)]bis[alkyl-

substituted alkanediol], polymer with alkylcarbonate, alkanediols, substituted alkanoic acid and isocyanate and alkyl substituted carbomonocycle, sodium salt (PMN P-18-102) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f), (j), and (o).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.

#### **§ 721.11287 Castor oil, reaction products with soybean oil.**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as castor oil, reaction products with soybean oil (PMN P-18-116) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(f) and (j). It is a significant new use to process or use the substance in any manner that generates an aerosol or mist. It is a significant new use to exceed the confidential annual production volume stated in the PMN.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

(3) *Determining whether a specific use is subject to this section.* The provisions of § 721.1725(b)(1) apply to paragraph (a)(2)(i) of this section.

**§ 721.11289 1-Butanaminium,N,N,N-tributyl-,2(or 5)- [[benzoyldihydrodioxo [(sulfophenyl) amino]heteropolycycle]oxy]-5(or 2)-(1,1-dimethylpropyl)benzenesulfonate (2:1) (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as 1-butanaminium,N,N,N-tributyl-,2(or 5)- [[benzoyldihydrodioxo [(sulfophenyl) amino]heteropolycycle]oxy]-5(or 2)-(1,1-dimethylpropyl)benzenesulfonate (2:1) (PMN P-18-136) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposure.

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=19.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of §

721.185 apply to this section.

**§ 721.11290 Alkylsilsesquioxane, ethoxy-terminated (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as alkylsilsesquioxane, ethoxy-terminated (PMN P-18-137) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposure.

(ii) *Release to water.* Requirements as specified in § 721.90(a)(4), (b)(4), and (c)(4), where N=58.

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c), (i), and (k) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

**§ 721.11291 Polythioether, short chain diol polymer terminated with aliphatic diisocyanate (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as polythioether, short chain diol polymer terminated with aliphatic diisocyanate (PMN P-18-219) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture the PMN substance with molecular weight greater than 10,000 daltons. It is a

significant new use to manufacture the PMN substance with free isocyanate residuals greater than 0.01% by weight.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

**§ 721.11292 Alkenoic acid, polymer with alkenylcarbomonocycle, [alkanediylbis (substituted alkylene)] bis[heteromonocycle] and (alkylalkenyl) aromatic, salt (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as alkenoic acid, polymer with alkenylcarbomonocycle, [alkanediylbis (substituted alkylene)] bis[heteromonocycle] and (alkylalkenyl) aromatic, salt (PMN P-18-224) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposure. It is a significant new use to manufacture the substance to contain an acid content greater than 20% by weight.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (i) are applicable to manufacturers and processors of this substance.



(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

**§ 721.11293 Alkenoic acid, polymer with substituted alkyloxirane, alkenylcarbomonocycle, alkyl substituted alkyl alkanediol and (alkylalkenyl) aromatic, salt (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as alkenoic acid, polymer with substituted alkyloxirane, alkenylcarbomonocycle, alkyl substituted alkyl alkanediol and (alkylalkenyl) aromatic, salt (PMN P-18-225) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* It is a significant new use to manufacture, process, or use the substance in any manner that results in inhalation exposure. It is a significant new use to manufacture the substance to contain an acid content greater than 20% by weight.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (c) and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

**§ 721.11294 Alkyl alkenoic acid, alkyl ester, telomer with alkylthiol, substituted carbomonocycle, substituted alkyl alkyl alkenoate and hydroxyalkyl alkenoate, tertbutyl alkyl peroxyate-initiated (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified generically as alkyl alkenoic acid, alkyl ester, telomer with alkylthiol,

substituted carbomonocycle, substituted alkyl alkyl alkenoate and hydroxyalkyl alkenoate, tertbutyl alkyl peroxyoate-initiated (PMN P-18-233) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.* Requirements as specified in § 721.80(w)(2).

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) though (c) and (i) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

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**§ 721.11603 Substituted heteromonocycle, polymer with substituted alkanediol and diisocyanate substituted carbomonocycle, alkylene glycol acrylate-blocked (generic).**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance generically identified as substituted heteromonocycle, polymer with substituted alkanediol and diisocyanate substituted carbomonocycle, alkylene glycol acrylate-blocked (PMN P-18-279) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) *Protection in the workplace.* Requirements as specified in § 721.63(a)(1), (4), and (5). For purposes of § 721.63(a)(4), only persons subject to inhalation exposure from spray application of the chemical substance are subject to these requirements. When determining which persons are reasonably likely to be exposed as required for § 721.63(a)(4), engineering

control measures (e.g., enclosure or confinement of the operation, general, and local ventilation) or administrative control measures (e.g., workplace policies and procedures) shall be considered and implemented to prevent exposure, where feasible. For purposes of § 721.63(a)(5) respirators must provide a National Institute for Occupational Safety and Health assigned protection factor of at least 1000.

(ii) [Reserved]

(b) *Specific requirements.* The provisions of subpart A of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 721.125(a) through (d) are applicable to manufacturers and processors of this substance.

(2) *Limitation or revocation of certain notification requirements.* The provisions of § 721.185 apply to this section.

## **PART 725--REPORTING REQUIREMENTS AND REVIEW PROCESSES FOR MICROORGANISMS**

5. The authority citation for part 725 continues to read as follows:

**Authority:** 15 U.S.C. 2604, 2607, 2613, and 2625.

6. Add § 725.1079 to read as follows:

**§ 725.1079 Arsenic detecting strain of *E. coli* with extra-chromosomal elements, including an intergeneric screening marker (generic).**

(a) *Microorganism and significant new uses subject to reporting.* (1) The genetically-modified microorganism identified generically as arsenic detecting strain of *E. coli* with extra-chromosomal elements, including an intergeneric screening marker (MCAN J-18-41) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) The significant new uses are:

(i) It is a significant new use to manufacture (excluding import) the microorganism in the

United States for any use.

(ii) It is a significant new use to use the microorganism other than to detect arsenic in small water samples.

(b) *Specific requirements.* The provisions of subpart L of this part apply to this section except as modified by this paragraph (b).

(1) *Recordkeeping.* Recordkeeping requirements as specified in § 725.950(b)(2) through (4) are applicable to manufacturers and processors of this microorganism.

(2) *Modification or revocation of certain notification requirements.* The provisions of § 725.984 apply to this section.

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